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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/192,579	11/17/1998	FRANCO MENOZZI	960-34	9973

7590 02/13/2003

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EXAMINER
SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
1645	27

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/192,579	MENOZZI ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10January2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): ___.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached Detailed Action*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *none*.

   Claim(s) objected to: *68-70*.

   Claim(s) rejected: *56-67*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

DETAILED ACTION

1. Applicants' Response to Final Office Action, received 10January2003, paper#26, is acknowledged.

2. Claims 56-70 are pending and under consideration.

Rejections Maintained

3. The rejection of claims 56-67 under 35 U.S.C. 102(b) as being anticipated by Menozzi et al (*Abstracts of the General Meeting of the ASM*, 95(0):193, abstract B-159) is maintained.

Applicants argue that the instant claims make reference to a particular sequence, but that Menozzi et al does not provide said amino acid sequence.

Applicants argue that Menozzi et al do neither define nor characterize the monoclonal antibodies used. Thus, one skilled in the art would have insufficient information to identify the 28kDa protein.

Applicants argue that because the experimental conditions of the chromatography used by Menozzi et al are not described, one of skill in the art could not distinguish laminin-binding protein (which has the same molecular weight as heparin-binding haemagglutinin type antigen) and HBHA.

Thus, Menozzi et al does not teach nor suggest the claimed invention.

The examiner has considered applicants' arguments, but does not find them persuasive because a comparison of the characteristics and scientists involved in determining the characteristics indicate that the isolated proteinic mycobacterial antigen of the instant claims and

of the cited reference are identical. As such, the amino sequence of the isolated proteinic mycobacterial antigen would be an inherent property.

Instant Specification/claims		Cited Reference
Scientists:	FD Menozzi, C Locht	FD Menozzi, C Locht, JH Rouse, M. Laud-Sharp, MJ Brennan
Laboratories:	Institute Pasteur, Lille, France	Institute Pasteur, Lille, France and FDA, Bethesda, MD, USA
Name:	Heparin-Binding Hemagglutinin(HBHA)	Heparin-Binding Hemagglutinin(HBHA)
Source:	M. bovis BCG, *M. tuberculosis*	*M. bovis* BCG, *M. tuberculosis*
MW:	28kDa	28kDa
Chromatography:	heparin-Sepharose	heparin-Sepharose
Location:	surface of mycobacteria	surface of mycobacteria
Effect on attachment to Epithelial cells:		
	inhibited by sulphated glucides	inhibited by sulphated sugars
	not inhibited by nonsulphated sugars	not inhibited by nonsulphated carbohydrates
Effect on attachment to erythrocytes:		
	inhibited by sulphated polysaccharides	inhibited by sulphated polysaccharides
	not inhibited by nonsulphated sugars	not inhibited by nonsulphated sugars
antigen 85 complex:	not related	not related

Thus, it is assumed that the HBHA of the instant claims and the HBHA of the cited reference are identical because: 1) the instant inventors and their laboratories are also authors on the cited reference, 2) both proteins have the same name, and 3) both proteins have identical characteristics. Therefore, the amino sequence of the cited reference HBHA and its binding to specific monoclonal antibodies would be identical to the HBHA of the instant claims.

4. Claims 68-70 are objected to as being dependent from rejected claims.

Conclusion

5. No claims are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

February 13, 2003